

REJECTION UNDER §102

Claims 27- 29 have been rejected under 35 U.S.C. §102(b) or §102(e) as being anticipated by Barnes (U.S. 4,721,723) or Ward et al. (U.S. 5,872,132). This rejection is respectfully traversed.

The presently claimed subject matter (claims 27-29) is indistinguishable from the subject matter patented in claims 2 and 4 of U.S. Patent 6,063,927 (Craig et al.). On this basis, applicants traverse the instant rejection.

The Examiner argues that the products of Craig and the instant claims 27-29 may not be identical because anhydrides, hemihydrates, solvates, etc., can be patentably different products. But claims 2 and 4 of Craig do not contain any language limiting the hydration state of the paroxetine hydrochloride or requiring it to be a solvate. While the choice of solvent could affect such properties, claims 2 and 4 of Craig do not recite the presence of a solvent, much less a particular solvent, nor crystallization. Thus, all of the forms of paroxetine hydrochloride suggested by the Examiner are apparently included within claims 2 and 4 of Craig. Similarly, instant claims 27-29 do NOT specify a solvent for the forming of paroxetine hydrochloride and instead use the same “contacting” language as in Craig claims 2 and 4. In short both the Craig claims and instant claims 27-29 are product-by-process claims directed to forming any paroxetine hydrochloride product from paroxetine methane sulfonate. There is no species-genus distinction in the scope of the Craig claims and the instant claims as the Examiner suggests. Thus, to the extent the USPTO has patented the subject matter of instant claims 27-29, albeit in the Craig patent, the present claims are patentable and reconsideration and withdrawal of this rejection are respectfully requested.

REJECTION UNDER §103

Claims 24 and 25 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stemp et al. (EP 190,496) in view of Barnes et al. (U.S. 4,721,723). This rejection is respectfully traversed.

Claims 24 and 25 are directed to a process that uses as a starting material a novel, patentable compound, namely paroxetine methane sulfonate.<sup>1</sup> Because selecting paroxetine methane sulfonate was itself unobvious and hence patentable, it follows that any use of such a compound is likewise unobvious and patentable. See *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995)(all limitations must be considered in determining obviousness, including the specified starting material). Therefore, the claimed process, which uses an unobvious starting material, is patentable.

Moreover, Stemp fails to provide any motivation to carry out the process as claimed. It should be noted that Stemp is directed to compounds that differ from paroxetine. Page 1 of Stemp distinguishes the inventive compounds of formula (1) therein from the known phenyl-piperidines, citing the basic paroxetine patent. The pharmaceutically acceptable salts recited on page 3 of Stemp are directed to the compounds of formula (1), which compounds do not include paroxetine. Thus, the page 3 disclosure is irrelevant to the present invention; i.e. it neither teaches nor suggests paroxetine methane sulfonate nor contacting the same with hydrochloric acid to make paroxetine hydrochloride.

The Examiner's reliance on pages 51-52 of Stemp is similarly misplaced. This example illustrates how to resolve paroxetine by using optically active acids. Why would the worker of ordinary skill in the art replace the optically active tartaric acid of this example

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<sup>1</sup> The Examiner granted the grand-parent application, now US 5,874,447, which contains claims to, *inter alia*, paroxetine methane sulfonate.

with the non-optically active methanesulfonic acid as the Examiner proposes? Such a modification would destroy the point of the example, i.e. no resolution would be achieved. Therefore the page 51-52 disclosure does not suggest using applicants' claimed methane sulfonic acid salt because the desired resolution would not be achieved.

In short, nothing in Stemp suggests starting with a paroxetine methanesulfonate and converting it to paroxetine hydrochloride as per the present process claims. Again, Stemp does not generically teach paroxetine methanesulfonate because formula (1) of Stemp does not embrace paroxetine. There is no teaching or suggestion of the claimed starting material, much less the claimed process of using it. Barnes fails to overcome this shortcoming and is in fact relied upon simply to show that converting a paroxetine salt is possible. Such a teaching does not direct the worker of ordinary skill in the art to select paroxetine methanesulfonate as the starting salt as is required by the present claims. Given the scope of the present process claims and the lack of any teaching or direction in the applied prior art to use paroxetine methanesulfonate, the presently claimed subject matter is clearly novel and unobvious.

Finally, applicants previously pointed out that the claimed process can have certain advantages such as providing for high purity. The fact that such advantages were, in the Examiner's words, "elucidated . . in hindsight" does not render such advantages obvious. It is the obviousness of the advantages that is pertinent here, and not the inherency thereof. If the average artisan could not have recognized the inherent advantage, then what would have motivated the formation of the claimed invention? Put differently, if the advantages were not obvious, then they are unexpected advantages, which are strong evidence of

non-obviousness. In any event, the Examiner's rejection fails to establish a *prima facie* case of obviousness in the first place and unexpected results are not legally required.

Given that Stemp fails to teach or suggest the applicants' specifically claimed starting material and further fails to teach or suggest contacting such a starting material with hydrochloric acid, Stemp is factually incapable of rendering the presently claimed invention *prima facie* obvious. Since Barnes does not overcome this basic deficiency, the Examiner's rejection fails to establish obviousness within the meaning of 35 U.S.C. § 103. Accordingly reconsideration and withdrawal of this rejection are respectfully requested.

### CONCLUSION

In view of the remarks, reconsideration of the rejections and allowance of the application are respectfully requested.

Should the Examiner have any questions, regarding this application, she is encouraged to contact applicants' undersigned representative at 703 753 5256.

Respectfully submitted,



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Date: October 23, 2003